DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-45

April 6, 2000

Greg L. Marlow, Vice-President
Tan USA/The Optimum Group, Inc.
6783 Newberry Road
Gainesville, Florida 32605

Dear Mr. Marlow:

Inspections of two Tan USA facilities located at 3600 SW Archer Road, Suite B, Gainesville, Florida and 10771 Beach Boulevard, Suite 400, Jacksonville, Florida, completed on March 2, 2000 by FDA Investigator H. Randy Bringger, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant items of noncompliance with the Federal Performance Standards for Sunlamp Products prescribed in Title 21, Code of Federal Regulations, Part 1040.20 (21 CFR 1040.20) in conjunction with tanning beds in operation at those facilities.

Tan USA, Gainesville, Florida

Inspection revealed two Model 728 Wolff System Tanning Beds to be adulterated within the meaning of Section 501(c) of the Act in that both beds contain UV lamps which are not designated in the manufacturer's label instructions for use in the beds and the quality of those beds falls below that which they are represented to possess. No documentation was available to show that the UV lamps in use are compatible with the UV lamps recommended by the manufacturer and certified for use in the beds.

The inspection also revealed secondary 30 minute dial timers installed on the walls at the entrance to tanning rooms containing Models 728 and 624 Wolff System Tanning Beds. The maximum exposure time specified by the manufacturer for those beds is 20 minutes. You should take steps to ensure that these secondary timers cannot exceed the maximum exposure time specified by the manufacturer.

Tan USA, Jacksonville, Florida

Inspection revealed a Tan America Model VIP 3000 Sun Bed to be misbranded within the meaning of Sections 502(c) and 502(f) of the Act in that labeling fails to bear a manufacturer's certification label or tag as required by 21 CFR 1010.3, adequate directions for use and adequate warnings against use as required by 21 CFR 1040.20(d).

The inspection also revealed a Model 838/3 SonnenBraune Wolff Sun Bed to be misbranded within the meaning of Section 502(f) of the Act in that user instructions were not available to provide adequate directions and instructions for use in such manner as necessary for the protection of users against potentially harmful exposure to ultraviolet radiation as required by 21 CFR 1040.20(e).

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your TAN USA facilities. It is your responsibility to ensure that electronic sunlamp products in use at all Tan USA facilities meet applicable performance standards and comply with the provisions of the Act. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for delay and the period within which the corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderly Place, Suite 200, Maitland, Florida, 32751, telephone (407) 475-4731.

Sincerely,

Edward R. Atkins

Edward R. Atkins
Acting Director
Florida District